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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HANG-CHING LIN, JERMING TSENG, HSIOU-YU DING, WEN-LLANG CHANG, CHIEN-LIAN CHAO, and HSIN-WEN HUANG

Appeal 2009-008647
Application 10/717,559
Technology Center 1600

Decided: May 18, 2010

Before TONI R. SCHEINER, MELANIE L. McCOLLUM, and JEFFREY N. FREDMAN, *Administrative Patent Judges.*

SCHEINER, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the rejection of claims 6-13, directed to a *Poria* extract. The claims have been rejected on the grounds of obviousness and indefiniteness. We have jurisdiction under 35 U.S.C. § 6(b).

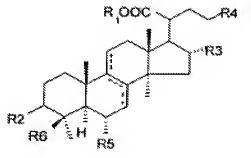
STATEMENT OF THE CASE

According to the Specification, "*Poria* extract has [a] tonic effect, as well as a smoothing effect on stomach disorder . . . [and] is classified as a tranquilizer and a uretic agent." In addition, "*Poria* extract has a favorable effect on tumor prevention, and . . . is beneficial to immunity enhancement and gastrointestinal system of a person suffering from a chronic disease." (Spec. 1: 11-20.)

Crude extracts of *Poria* can be separated into "a lanostane fraction and a secolanostane fraction" (Spec. 3: 19-20). According to Appellants, lanostanes "have an immunity enhancement effect" (*id.* at 3: 15), while secolanostane "has a toxic effect on rat spleen cells" (*id.* at 5: 15).

Claims 6 and 7 are representative of the subject matter on appeal:

6. A Poria extract capable of enhancing immunity of a mammal comprising 5-60% of a lanostane having the following chemical formula (I) by weight of the extract, and being substantially devoid of secolanostane:



(I)

wherein R_1 is either H or CH_3; R_2 is $OCOCH_3$, =O or OH; R_3 is H or OH; R_4 is $-C(=CH_2)-C(CH_3)_2R_a$, wherein R_a is H or OH, or $-CH=C(CH_3)-R_b$, wherein R_b is CH_3 or CH_2OH; R_5 is H or OH; and R_6 is CH_3 or CH_2OH.

7. The Poria extract according to claim 6, which is prepared by a method comprising the following steps:

a) extracting metabolites, fermentation products or sclerotium of Poria cocos (Schw) Wolf by water, methanol, ethanol, or a mixed solvent thereof;

b) concentrating the resulting liquid extract from step a);

c) introducing the resulting concentrated substance from step b) into a silica gel column;

d) eluting the silica gel column with an eluent having a low polarity, and collecting the resultant eluate;

e) concentrating the eluate to form a concentrated eluate.

The Examiner rejected the claims as follows:

- Claims 6-13 under 35 U.S.C. § 103(a) as unpatentable over Takahashi[1] and Tai.[2, 3]

- Claims 6-13 under 35 U.S.C. § 112, second paragraph, as indefinite.

We affirm the obviousness rejection, and reverse the indefiniteness rejection.

OBVIOUSNESS

Issue

Has the Examiner established that Takahashi teaches or suggests a *Poria* extract comprising 5-60% lanostanes of formula (I) by weight, and which is substantially devoid of secolanostanes?

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[1] Japanese Patent Application JP 8-119864 of Kunio Takahashi et al., published May 14, 1996 (all references herein are to the English language translation).

[2] Takaaki Tai et al., *Triterpenes from the Surface Layer of Poria cocos*, 39 PHYTOCHEMISTRY 1165-1169 (1995).

[3] A second obviousness rejection of claims 6-13 was withdrawn by the Examiner (Ans. 3).

Findings of Fact

FF1 According to the Specification, a crude extract of the fungus *Poria cocos* is obtained by a "conventional extraction process" (Spec. 3: 17), followed by "[a] chromatographic separation . . . to separate constituents of the crude extract, which include a lanostane fraction and a secolanostane fraction" (*id.*).

FF2 The Specification teaches that "[t]he lanostane fraction is relatively smaller in polarity than the secolanostane fraction" (Spec. 3: 20-21).

FF3 In addition, "[t]he position of the lanostane fraction is identified by the thin layer chromatography, which has a chromatographic value (Rf) . . . [of] 0.1 when a developing solution of dichloromethane : methanol (96:4) is used. The chromatographic value of secolanostane is smaller than 0.1" (Spec. 3: 24 to 4: 2).

FF4 Takahashi describes extraction of hoelen, derived from *Poria cocos* Wolf:

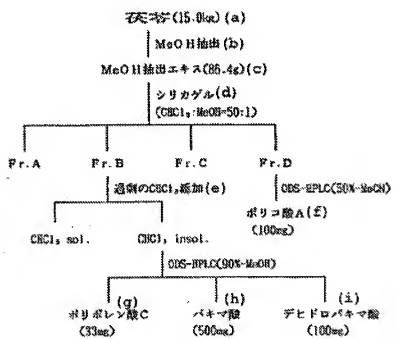
> Fifteen kilograms of hoelen was extracted with methanol . . . From the extraction solution obtained after filtration, the solvent was distilled away under reduced pressure, thereby obtaining 86.4 g of a methanol-extracted extract. Thereafter, using a silica gel chromatogram column having an inner diameter of 12 cm and a length of 80 cm, the extract was eluted with chloroform-methanol (50 : 1), thereby obtaining fractions A through D. Fraction A [sic, B] formed a precipitate when an excess amount of chloroform was added to it. This precipitate was subjected to reverse-phase preparative high-performance liquid chromatography repeatedly, using a 90% methanol as the solvent, thereby obtaining polyporenic acid C (33 mg), pachymic acid (500 mg), and dehydropachymic acid (100 mg).
>
> . . .

> The aforesaid fraction D was further subjected to silica gel column chromatography and reverse-phase preparative high-performance liquid chromatography repeatedly, thereby obtaining poricoic acid A (100 mg).

(Takahashi ¶ 11, 12.)

FF5 Takahashi's Table 1, reproduced below, illustrates the isolation and purification procedures discussed above in FF4:

TABLE 1



Takahashi's Table 1 illustrates isolation and purification procedures for the lanostanes polyporenic acid C, pachymic acid, and dehydropachymic acid, as well as the secolanostane porichoic acid A. Key: a) hoelen; b) MeOH extraction; c) MeOH-extracted extract; d) silica gel; e) add an excess amount of $CHCl_3$; f) porichoic acid A; g) polyporenic acid; h) pachymic acid; and i) dehydropachymic acid.

Analysis

Claim 6 is directed to a *Poria* extract "capable of enhancing immunity of a mammal comprising 5-60% of a lanostane having the . . . chemical formula (I) by weight of the extract, and being substantially devoid of secolanostane." Claim 7 is a product-by-process claim which depends directly or indirectly from claim 6.

According to the Examiner (referring to Table 1 and paragraph 11 of Takahashi):

> Takahashi produces a Poria extract using an extraction procedure that is substantially identical to the extraction procedure [recited] . . . in claim 7. The reference teaches extraction of hoelen . . . defined by the reference as being a portion of the sclerotium of *Poria cocos* . . . The hoelen is extracted with methanol . . . This corresponds to step a) in appellant's claim 7. The extraction solution is concentrated by filtration and then removal of the solvent . . . This corresponds to step b) in appellant's [sic] claim 7. The concentrated extract is then subjected to silica gel column chromatography . . . This corresponds to step c) in appellant's [sic] claim 7. The extract is then eluted with chloroform and methanol to obtain four fractions, termed Fractions A-D . . . The reference does not specifically define this eluent as a "low polarity" eluent. However, appellant's [sic] claim 8 states that the low polarity eluent contains methanol. The eluent used in the reference also contains methanol . . . Thus, the reference also teaches a step that corresponds to step d) in appellant's [sic] claim 7. Table 1 in the reference shows that fraction B is further concentrated using solvent fractionation. This corresponds to step e) in appellant's [sic] claim 7.

(Ans. 9.)

The Examiner finds that Takahashi's Table 1 shows that fraction B "contains polyporenic acid, pachymic acid, and dehydropachymic acid all of

which are lanostane compounds" (Ans. 9), while "secolanostane compounds are found in fraction D" (Ans. 9). The Examiner concludes that fraction B was "examined for secolanostanes and does not contain these compounds" (*id.* at 10), and therefore, "is 'substantially devoid' of secolanostane compounds" (*id.*).

In addition, the Examiner reasons:

> [S]ince the extraction procedure taught by the reference is substantially identical to the extraction procedure taught by the appellant [sic], it is reasonable to assume that the concentration of the lanostane compounds in the reference extract are at least overlapping, if not identical, to the percentages claimed by the appellant [sic]. Therefore, since the extract taught by the reference reasonably appears to be identical to the extract claimed by the appellant [sic], the reference extract would intrinsically have the same pharmaceutical properties as the claimed extract . . . [and] would have the same ability to "enhance immunity" as the claimed extract.

(Ans. 10.)

Appellants acknowledge that "[p]olyporenic acid C, pachymic acid, and dehydropachymic acid are all appropriate lanostane compounds of formula (I)" (App. Br. 8), but contend that "the Poria extract prepared by Taka[ha]shi contains 0.12% of secolanostane (formula 16, 100 mg in Fraction D)" (*id.*), and "no matter how the extract taught by Taka[ha]shi is optimized the ratio of secolanostane (0.12%) to the compounds (I) (0.73%) should remain about 0.12/0.73" (*id.*).

Appellants contend that the Specification "show[s] the Poria extract . . . comprising 5-60% of a lanostane by weight of the extract and being substantially devoid of secolanostane is capable of enhancing immunity of human body . . . [while] [t]he extract containing secolanostanes . . . is shown

to be inhibitive as to the immunity of human body" (App. Br. 9). Appellants contend that Takahashi "teaches that secolanostane is also a potent component" (*id.*), thus, "there is lack of motivation to prepare a *Poria* extract comprising 5-60% of a lanostane by weight of the extract and being substantially devoid of secolanostane" (*id.*).

Appellants' arguments are not persuasive because they fail to account for the fact that Takahashi further fractionated the methanol-extracted extract ((c) in Table 1) into fractions A-D. The Examiner's conclusion that Takahashi's fraction B is devoid of secolanostane is reasonable, given the fact that secolanostane was detected in fraction D, but Takahashi did not report the presence of secolanostanes in fraction B (FF4, FF5).

Moreover, Appellants have not identified any flaw in the Examiner's findings with respect to the correspondence between Takahashi's extraction procedure (Ans. 9) and the extraction procedure outlined in product-by-process claim 7. Therefore, we agree with the Examiner that it is reasonable to conclude that the percentage of lanostane compounds in Takahashi's fraction B falls within 5-60%, by weight, and that fraction B "would have the same ability to 'enhance immunity' as the claimed extract" (Ans. 10). Appellants have not established otherwise by argument or evidence.

Conclusions of Law

The Examiner has established that Takahashi teaches or suggests a *Poria* extract comprising 5-60% lanostanes of formula (I) by weight, and which is substantially devoid of secolanostanes.

INDEFINITENESS

The Examiner rejected claims 6-13 as indefinite because "the term 'substantially' . . . is a relative term" and the "[t]he specification does not provide any definition or guidelines that could be used to determine what amounts of secolanostane could be present in the extract and still have the extract be considered 'substantially devoid of secolanostane'" (Ans. 7). The Examiner finds the term "'low' in reference to the eluent polarity" to be indefinite on similar grounds (*id.* at 8).

Nevertheless, we are persuaded by Appellants' arguments, set forth on pages 5-7 of the Reply Brief, that one skilled in the art would "know the meaning of substantially devoid of secolanostane which has an adverse effect [on immunity development] and is remove [sic] according to the technique disclosed in . . . the specification" (Reply Br. 6). Similarly, we are persuaded that the Specification "provides . . . a specific composition is provided the polarity of which can be determined . . . [which] provides one of ordinary skill in the art with the necessary guidance as to the meaning of low polarity of the eluent" (*id.* at 7).

SUMMARY

- The rejection of claims 6-13 under 35 U.S.C. § 103(a) as unpatentable over Takahashi and Tai is affirmed.
- The rejection of claims 6-13 under 35 U.S.C. § 112, second paragraph, as indefinite is reversed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

clj

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